Summary of the Meeting of the CON Task Force

June 23, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members Present

Commissioner Robert E. Nicolay, CPA, Chairman
Commissioner Larry Ginsburg
Alan Bedrick, M.D.
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Annice Cody
Hal Cohen, Ph.D.
Natalie Holland
Carlessia A. Hussein, DrPH
Adam Kane, Esquire
Michelle Mahan
Anil K. Narang, D.O.
Lawrence Pinkner, M.D.
Barry F. Rosen, Esquire
Joel Suldan, Esquire
Jack Tranter, Esquire
Douglas H. Wilson, Ph.D.

Task Force Members Absent

Commissioner Robert E. Moffit, Ph.D.
Patricia M.C. Brown, Esquire
William L. Chester, M.D.
Henry Meilman, M.D.
Frank Pommett, Jr.
Christine M. Stefanides, RN, CHE
Terri Twilley, MS, RN

Members of the Public Present

Heather Barthel, Johns Hopkins Medicine
Clarence Brewton, MedStar Health
Andrew Cohen, AGC and Associates

Carolyn Core, Civista Health, Inc.
Jack Eller, Esquire, Ober, Kaler, Grimes, & Shriver
Sean Flanagan, St. Joseph Medical Center
Richard Gasparotti, Adams Management Services
Christopher Hall, Adventist Healthcare
Wynee Hawk, Greater Baltimore Medical Center
Donna Jacobs, University of Maryland Medical System
Anne Langley, Johns Hopkins Health System
Frank Monius, MHA: Association of Maryland Hospitals & Health Systems
Martha Nathanson, LifeBridge Health
Vanessa Purnell, MedStar Health
Laura Resh, Carroll Hospital Center
Andrew L. Solberg, A.L.S. Healthcare Consulting & Services
Pegeen Townsend, MHA: Association of Maryland Hospitals & Health Systems
Elizabeth Weglein, MNCHA

1. Call to Order

Chairman Robert E. Nicolay called the meeting to order at 1:05 p.m. and welcomed Task Force members and the public.

2. Approval of the Previous Minutes (May 26, 2005 and June 7, 2005)

Chairman Nicolay noted that the Task Force members had received copies of the minutes of the May 26, 2005 and the June 7, 2005 meetings and asked for any comments, changes, or corrections. A motion was made and seconded to approve the May 26, 2005 minutes of the Task Force, which was unanimously approved. A motion was made and seconded to approve the June 7, 2005 minutes of the Task Force, which was also unanimously approved.

3. Review and Discussion of the Public Comments Received on the CON Program

Chairman Nicolay announced that the first topic of review and discussion was a summary of the major issues raised in the public testimony and written comments received. He provided an overview of the comments submitted to the Task Force, by health care service. The Task Force received seventeen comments regarding acute care services; as well as comments on hospice services, home health services, nursing homes, ambulatory surgery, and the capital expenditure threshold.

The Chairman said that, together with the staff, he had reviewed all of the comments and had assembled them by category. He added that the Task Force would consider the first group of comments, on coverage. In that group, there were nine comments in favor of retaining Certificate of Need (CON) with no changes; nineteen comments in favor of retaining CON but changing coverage; and fourteen comments recommending deregulation of some or all services or actions. On the subject of a re-focus of completeness review, the Task Force received ten comments. Additional comments were received regarding changing the capital threshold and simplifying or expediting the review process. In addition, many recommendations received (comments from sixteen people) related to updating the State Health Plan standards. Five comments were received recommending the adoption of a licensure formula for bed need; and three comments were received regarding monitoring and enforcing compliance with CON.

Chairman Nicolay summarized the comments received regarding coverage by CON review and noted that one of the major issues was acute care hospitals. The first item in this area was a recommendation to remove CON coverage for Obstetric Services, as well as comments recommending the substitution of licensure for CON review in some highly specialized services. It was also recommended that the Task Force consider adding CON coverage for Emergency Department services and cardiac catheterization laboratories. Another recommendation was for raising the capital threshold to at least $7.5 million, with individual hospital commenters advocating a $10 million threshold. Various commenters recommended the expansion of the CON business office equipment exemption to include health information technology.

The Chairman then discussed long term care services. On the subject of hospice services, the Task Force received six comments in favor of maintaining a strong CON program, and three comments in favor of deregulation. On the subject of home health agencies, three commenters favor no change to CON; two commenters reached no consensus among their member-agencies on CON coverage but favor stronger enforcement of regulatory authority through more frequent "surveys," and two commenters favor deregulation. Comments received on nursing homes included increasing the capital expenditure threshold, and proposing that the closure of a facility should not require CON review, or should be part of a comprehensive review of a CON project to relocate and re-use nursing home beds.

Chairman Nicolay recommended that the major issues reflected in the comments be considered and discussed by the Task Force with the goal ideally of reaching consensus on recommendations in these areas. Chairman Nicolay reiterated the timetable for recommendations to be made to the Commission in September. Due to the number of topics suggested for consideration, the Chairman urged the Task Force members to keep their comments succinct and on-target.

● **Hospice Services**

The Chairman announced that the Task Force would turn its attention to consideration of hospice services. He noted that consideration of home health services would be deferred to the next meeting (on July 14, 2005) because Task Force member Terri Twilley was unable to attend the June 23rd meeting. Chairman Nicolay urged the Task Force members to participate in making comments and suggestions, debate among themselves, and reach consensus on each item.

Alan Bedrick, M.D. said that his assessment of the testimony was that the current system is working well for hospice services. If the Commission were to deregulate hospice, there would be some deterioration of services. In his opinion, the Commission should maintain the current CON regulation of hospice services.

Hal Cohen, Ph.D. suggested elimination of CON for hospice services because the reasons for CON, largely, do not apply to hospice. In his view, there is very little relationship to capital investment and there is no reason to limit capacity. Terminally ill patients should have the opportunity to use hospice services; therefore, as an agency, the Commission should not care about how many hospices are available. According to Dr. Cohen, the result of current regulation creates a moratorium on new hospice providers. The preference should be in favor of competition, unless there is other evidence showing that it does not work. Dr. Cohen interpreted the hospice providers' arguments in favor of CON regulation as arguments for protection from competition, which, in his opinion, is not an appropriate basis for CON regulation.

Albert L. Blumberg, M.D., F.A.C.R. agreed with Dr. Cohen, adding that CON, in general, eliminates competition, creates monopolies, and does not allow the marketplace to help or encourage a provider to improve services. There is a concern for providers in rural areas that if CON regulation is eliminated, they will lose some type of a protective shield and might have a problem with maintaining solvency. For many hospices, the average length of stay is seven to ten days, often due to patients' difficulty in accepting their medical status and their need for these services, which is not the best utilization of hospice benefits. He added that as a society, we would be better off if patients more fully utilized hospices, though that is not the function of the CON process. As there are outside agencies, separate from state agencies, that evaluate and certify hospice providers, Dr. Blumberg stated that he does not see the value of CON for hospice services.

Lynn Bonde said that all of Maryland's hospice providers support retaining the CON for many reasons. In Baltimore, Montgomery, Prince George's, and Anne Arundel counties, and Baltimore City, there are a number of hospices. Any possible benefits from competition are available in areas where there is sufficient population to support multiple hospices. Of the thirty hospices in the state, twenty-seven or twenty-eight are not-for-profit organizations. Those organizations do not survive without charitable donations. There is competition for both volunteers and for charitable donations.

Ms. Bonde added that in Calvert County, the Calvert Hospice provides free community-wide bereavement services and that this is the case for a number of hospices. The services that hospices provide support community needs beyond simply caring for terminally ill patients. There is a quality baseline incorporated into the CON regulations. Marketplace entry is available through purchase and merger. There are many hospice providers in those states that have eliminated, or never regulated, hospice care, though there is no evidence that more hospices mean better cost control. The classic economic argument—more competition results in lower costs—does not happen. Hospice is basically a fixed cost service, except where issues of patients' needs come into play. The very limited data available shows that hospices in non-CON states do not provide as much patient care, do not provide as many visits, and do not provide as many dollars toward the high cost of pharmaceuticals.

According to Ms. Bonde, CON is one of several ways to ensure that the quality of hospice care is maintained. In addition to the state's licensure laws, most of the hospices in Maryland are JCAHO-accredited; however, unlike hospitals, this is not a requirement. General hospice providers are also Medicare-certified, which adds assurance of compliance with a set of quality conditions. Thus, there are many spurs to improving and sustaining high quality in hospice processes.

In Ms. Bonde's view, throwing out a system that has supported hospice and its growth in the state on the basis of an economic theory that does not relate to the experience of the organizations that have operated under the CON program, without considering the adverse consequences to hospice providers and their patients, seems to be cavalier. The program has promoted competition where competition is warranted and has encouraged hospices in less densely populated areas to thrive.

Adam Kane, in concurring with Dr. Cohen's opinion, said that if the purpose of CON is to protect the state's capital investment, then CON applications should be evaluated based on the extent of state capital investment. He cited as an example, Erickson Retirement Communities' current issue with the Commission regarding hospice care. In his opinion, innovation is being stifled because of the CON process. There are exceptions that permit Erickson to care for its residents in nursing home beds, home health care, assisted living, and independent living arrangements. The only component of the senior care continuum that Erickson cannot operate is a hospice program. People come to Erickson from independent living, and Erickson provides for their health care needs in assisted living, skilled nursing, and home health care. For hospice services, Erickson must contract with other providers. In his view, there is no consistency or rationale for this rule other than to protect the "monopolist interests" of current hospice providers. Since there is no capital component to hospice, the existing hospices can continue to expand by adding personnel. According to Mr. Kane, the CON program for hospice services stifles innovation and is inconsistent with exceptions to the CON process granted in other areas.

Annice Cody said that the Commission did an extensive review of hospice services and recommended, after evaluating a set of public comments, to maintain CON for hospice services in 2001. She asked what has changed in the marketplace in the way hospice is delivered, or in any other aspect, that would lead the Task Force members to a different conclusion in 2005. Ms. Cody suggested that the Task Force members respect the extensive work that was done in 2001 and if there have been changes, then those changes should be considered.

Dr. Blumberg responded that he read the 2001 study. In his opinion, the difference is that the Commission's staff has driven every prior analysis of CON. In his view, the staff has a different perspective than the stakeholders. He recommended considering how people that are affected by CON view the benefits of CON. Are there economic arguments and state policy arguments that need to be taken into account, regardless of the service?

Jack Tranter said that in reading the comments, he was concerned about the relationship between charitable giving and viability because there was some suggestion that weakening the ability, or lessening the amount of money contributed to hospice, would be problematic in terms of continuity of service. He asked Ms. Bonde to address the relationship between charitable giving and hospice viability, as well as to respond to what she thinks would happen if hospice services were eliminated from the CON program.

Ms. Bonde replied that the relationship between charitable giving and viability is direct for not-for-profit hospices. There is more than a subjective difference in what would happen if CON were eliminated. The capacity of locally accountable, locally based hospice programs to serve the population would shrink. Services like bereavement care (a service that is not provided by the state on free or low-cost cases, but is provided by hospices) would essentially evaporate. Hospice programs would not be able to provide children's grief services, adult support groups, and individual counseling, without charitable dollars to support those programs. Studies show that the percentage of for-profit providers rises in states that eliminate CON coverage as well as in those states that do not have a CON program. She recently read an article that suggested that for-profit hospices, being quite rightly concerned with profits, tend to spend less on care than not-for-profit hospices.

Ms. Bonde added, in response to Mr. Tranter's question regarding the difference in scope of services provided by for-profit and not-for-profit hospice providers, that analysis has shown that the least expensive patients—those with the least costly medication needs and with the least costly staff needs—would be the patients that would go to the for-profit hospice providers due to "cherry picking". Hospice is, by statute, a comprehensive program. It is different from any other health care service provided by hospitals, home health, or ambulatory surgery providers because it involves psychosocial care, medical care, volunteer support, and bereavement follow-up for families, as required by statute and regulations. In addition, hospices are paid on a per diem basis for providing all of those services. Costs can be cut by reducing the cost of medications for patients, reducing the number of staff hours allocated to patients, and reducing the number of direct-cost items provided to patients. Ms. Bonde offered to provide a study to the Task Force as a later submission, which demonstrates that for-profit hospices tend to operate on a lower cost basis. She asserted that the CON program enables the existing structure to survive. Absent CON, national organizations that are not locally accountable, and some others that carry thousands of patients and have operations in many locations across the country would move in and begin to "cherry pick" the patients who are the lowest cost patients, leaving the patients whose medication needs and whose needs for intensive staff time are more expensive to the rest of the providers. In terms of competition, such a situation would weaken the existing structure.

Mr. Kane said that it seems that any time another organization, whether it is for-profit or non-profit, local or out of state, wants to provide hospice services, the hospice community is opposed. In his opinion, the CON structure in place would not ever permit a new provider to emerge. Ms. Bonde replied that there have been new providers since the CON report in 2001 was issued. For example, Seasons Hospice from Chicago moved into the area and Community Hospice moved out of the District of Columbia and into Maryland. Need was projected under the State Health Plan in Prince George's County. In addition, Capital Hospice acquired a hospice in Prince George's County and moved into Maryland from Northern Virginia. It is inaccurate to say that entry is completely barred, and that is not the objective of the current hospice providers. In Ms. Bonde's view, having operated under the existing regulatory structure, these changes have been reasonable and measured. The hospice providers' objective is to be able to sustain the existing hospice population in terms of local control and in terms of the quality of services provided.

Dr. Blumberg reiterated his original position, adding that he had a patient in need of hospice care that has refused that suggestion from his attending physician, the medical oncologist, as well as from him. He agreed with Mr. Tranter that the reason hospices have to depend so much on charitable giving is the length of stay issue. Up front costs are very intensive during the first week of hospice care and if the patient is not in the program long enough, then the program cannot recoup those costs. He added that Ms. Bonde was correct that with less funding, hospice programs would be unable to provide the ancillary services that make hospice such a positive experience for patients and families. As someone who refers patients to hospice on a regular basis, he asked for further information about cherry picking. Ms. Bonde explained that cherry picking is about making clinical choices on the basis of what is going to be the most profitable. Families of patients like the one that Dr. Blumberg described would eventually decide that they want that patient to come into hospice, perhaps two days before the patient was to die. A patient in that status would probably be rejected by a hospice that is looking to save the money that it would cost to provide all of the services for that very short term and very expensive patient; however, for longer-stay patients, they might provide fine care. Dr. Blumberg emphasized that he would never make another referral to a hospice provider that refused to provide care for one of his patients. He thought that many doctors would feel the same way.

Commissioner Larry Ginsburg observed that the discussion was leading to a disturbing and incorrect “all or nothing” approach. There was a great deal of validity in the Commission’s 2001 report, which included written testimony from all interested parties. In his view, the 2001 report was not “staff-driven”. He suggested that the Task Force use the 2001 report as a baseline and determine what has changed since that time.

Mr. Tranter asked about the benefits of eliminating CON for hospices. If opposition to CON is purely theoretical, in his opinion, then the Commission should not risk deregulation. In response, Dr. Blumberg said that the advantages for eliminating CON for hospice, other than the potential for more providers, included providing some continuity for people already in the system. In addition, there is something positive about having less regulation if the regulations are not providing any benefit. He added that he recognized the point made by Ms. Bonde that a finite donor pool that is spread out over more entities will affect that additional important cash resource. Dr. Blumberg added that if the hospice industry strongly determined that Maryland needs to maintain CON, then he would not remain opposed to the regulatory program.

Barry Rosen asked whether things are different in Garrett County or Calvert County than in Baltimore City. Is there a different down-side for the provider in a metropolitan area versus a rural area if CON went away? Ms. Bonde responded that the issues were population-based morbidity and mortality, and the potential pool of hospice patients. She said that it is an enticing notion to think that more hospices mean that more people would take advantage of hospice services, but that is a false conclusion because the availability of services is not the issue keeping people from coming into hospice. Rather, it is the profound reality of confronting death—a much more difficult and much more painful issue for people. For rural providers, the number of patients who would be appropriate for hospice that they have to draw from is smaller. In Prince George’s County or Baltimore City, the population is larger and that population can sustain more providers. The critical, and only, way that the State Health Plan identifies hospice need is through analysis of population morbidity and mortality data. The methodology utilized identifies probable future utilization based on analysis of trend data on hospice utilization and patient characteristics. If growth were projected, then an additional program would be considered for the jurisdiction. Ms. Bonde said that to criticize the system by saying that hospice is infinitely expandable by adding staff denies the reality of hospice providers in jurisdictions like Montgomery, Prince George's, Anne Arundel, and Baltimore Counties and Baltimore City. Mr. Kane's comment about innovation raised the same kind of issue that Mr. Tranter raised, i.e., the benefit for people in retirement communities who are now being served by their local hospices very well, versus an incalculable result. In Ms. Bonde's view, the issue is not restraining market entry, but looking at the potential impact on the people who are going to be served.

Mr. Kane replied that Erickson's proposal did not clarify what type of hospice product it would offer because, under the current regulations, they are not permitted to provide the services. He said that health systems and other organization have only begun designing elder care and senior care services. These organizations will be making major changes and major investments, and to the extent that regulation stifles creating programs, Maryland will be left behind other states. He cited, as an example, the hospices Erickson contracts with do not have the capacity to work with their residents' electronic medical records. Unless the hospice community comes along, or someone else can provide those services, the best quality of care will not be provided.

Ms. Bonde agreed that innovation is critical. She asked if Erickson would hire and sustain a full-time grief counselor and a full-time volunteer to sit with patients, as well as other ancillary and auxiliary services. Mr. Kane said that Erickson provides many of those services through its current hospice provider. Currently, Erickson must get a contractor instead of moving forward with the potential of establishing a different way—a more targeted hospice program—for its residents. Mr. Kane reiterated that Erickson had not been denied a CON for hospice services because there is no mechanism to apply for an exclusion from CON to serve its internal population in an integrated fashion under the current regulations, as there is in home health and nursing homes services.

Douglas H. Wilson, Ph.D. suggested that the Chairman poll the members, as each Task Force member had not yet expressed his/her opinion on hospice. Carlessia A. Hussein, DrPH, emphasized her dislike for making recommendations, taking positions, and considering issues when other stakeholders who are not necessarily concerned with the profitability of the service were not present. In her opinion, there was not enough information to make a judgment call. Dr. Hussein agreed with Dr. Wilson on the need for taking a straw vote.

Chairman Nicolay asked if the Task Force members wanted more information before making a recommendation. He determined that to facilitate making an informed resolution, the staff would summarize the day's discussion and provide any additional information available for consideration at a subsequent meeting. Dr. Hussein requested that someone provide information about what is broken in the hospice system so that the Task Force members will know what is not working. She asked for information on how need is being met, given the Commission's best ability to determine what the need is.

Commissioner Ginsburg noted that the 2001 study regarding hospice services had been included in the written comments provided to the task force members. He added that the

Commission's entire 2001 study of the CON program was posted on its website and urged the Task Force members to review it. In his view, any question about what has changed since 2001 was important to answer. Dr. Cohen posed additional considerations. To what extent should the decision be driven by what the industry wants, as opposed to what is appropriate public policy? Secondly, what is broken in Maryland and what is broken in states that do not have CON? Dr. Pinkner asked where it was possible to discuss a middle ground. For hospitals, ambulatory surgery, and other services, there are ways of tightening CON, loosening it, or changing some of the parameters. For hospice services, he questioned whether there is only one choice (i.e., to have a regulatory system or not).

Chairman Nicolay said that other states' data would be provided to the members of the Task Force. Following further discussion, he tabled the hospice issue and announced that the next item for discussion was closure of health care facilities.

●Closure of Health Care Facilities

Pamela Barclay briefed the Task Force members on the issue. Ms. Barclay said that some of the comments received related to the coverage by CON for facilities that are closing, particularly nursing homes. With respect to hospitals, depending on where the hospital is located, they are required only to provide notification to the public, or to make an exemption request to the Commission. One of the comments received would be to eliminate CON coverage for closure actions involving other types of health care facilities, in particular, nursing homes.

Dr. Blumberg asked Ms. Barclay to explain, in the acute hospital setting, how the exemption process functions in a closure situation. Ms. Barclay replied that the exemption provisions (that the proposal not be inconsistent with the State Health Plan, be in the public interest, and result in more cost effective care) apply in jurisdictions with fewer than three hospitals. For a hospital in a jurisdiction with three or more hospitals, closures require notification of the public. In a rural jurisdiction that has one hospital, there are more profound implications in terms of access and other issues that are of a public policy concern. There are no interested parties in an exemption proceeding. Ms. Barclay also noted that an exemption is a lower level of review than a full CON review.

Mr. Tranter said that he recognized the public policy concern for not having a hospital go away in a single hospital jurisdiction, but he could not see how the Commission could force that hospital to continue providing services. A number of hospitals, for example, have closed sub-acute care units. Hospitals in jurisdictions with three or more hospitals were required to tell the Commission they were closing and hold a public informational meeting that was sparsely attended. In a jurisdiction with fewer than three hospitals, a hospital was required to go through the closure process described by Ms. Barclay. His perspective was that the CON process cannot force a health care provider to continue to operate. He recommended that the Commission make the statutory changes required to change the process.

Natalie Holland added that the policy should apply to nursing homes as well as hospitals. From a nursing home's perspective, the closure is often coupled with the relocation of beds to another area or to another provider. Currently, two separate CON filings are required (one for closure and one for bed relocation) , resulting in additional costs.

Dr. Hussein asked whether part of the reason for reviewing closures was to insure that there is notification throughout a community, both for other providers of a similar nature and for the general public that might be using the facility. She suggested that there are other mechanisms, short of the CON process, to insure that that notification takes place. Ms. Barclay responded that notification is part of the issue. In addition, which services are offered by the facility would be an issue. Both facilities, and major services within facilities, would be subject to these kinds of rules. She cited the example of psychiatric services, where there are reimbursement issues in addition to difficulties providing the service.

Joel Suldan said that it seems that one of the ways to improve the entire CON process is to avoid regulatory proceedings whose outcome is essentially assured from the beginning. He asked if the Commission has ever turned down an application for closure. Ms. Barclay replied that she could not recall an application that had been turned down since she has been involved in the process. Closing major community institutions is a very difficult process; however, both for the community and for the hospital. In response to a question from Mr. Kane about duplication of regulatory processes, Ms. Barclay replied that there are provisions in the licensing process, in addition to other resources, for the transition of residents of nursing homes to other facilities. These are consumer protections built into the system for residents of health care facilities. The rules are different for hospitals because patients do not reside there.

Mr. Kane suggested that the Task Force look at duplicative functions among the CON process and the licensing agencies and make recommendations to decide which agency should be the primary agency in order to reduce some of the paper work.

Dr. Blumberg asked for more information regarding the requirements of notification. Ms. Barclay replied that hospitals are required to hold a hearing to inform the community that a closure is taking place and how it plans to proceed. They are also required to place a notice of closure in a local newspaper. Dr. Blumberg said that he did not understand the reason for requiring additional steps when the state is not prepared to deal with the economic issues that led the facility's management team to recommend closure. Dr. Cohen emphasized that it is not a management team, but the facility's board of directors, that makes a closure decision. Boards of Directors care about the community and would not choose to close facilities or services without good reasons. Therefore, only the notification process should be required. He recommended that the Task Force members vote on the issue.

Dr. Pinkner said that he had qualms about the closure of a service. If a hospital decides that psychiatry is not profitable, and the emergency room is not profitable, and obstetrics is not profitable, and so on, and then decides to become a surgical hospital or a specialty hospital, is it the Task Force members' suggestion to eliminate CON and permit the hospital to pick the services that they want to keep? Mr. Kane replied that it would be unlikely or unprecedented for the state to decide something like that. If the state is actually not going to have to decide differently, or to have an active role, then to go through the CON process does not make sense when the goal is simply to notify people that a facility is closing. Dr. Pinkner asked if the

Commission had stopped the closure of any individual services. Commissioner Ginsburg responded that he could not recall the Commission ever denying approval of a closure that was brought before it. He pointed out that the Commission is often notified about a closure long after the fact, and suggested that the Task Force members consider these issues in different sections. For example, it seemed clear that for nursing homes there is no justification for having the closure requirement followed by people having to transfer the beds to another nursing home. However, the CON procedures should be retained for specialty services.

Mr. Tranter said that he thought Dr. Pinkner was correct in a theoretical sense. If there were a service that was necessary to the community, provided by a hospital, then the Commission would have more leverage under the current rules. In a practical sense; however, the likelihood of that circumstance arising is remote because most of Maryland's hospitals are not-for-profit and would not close a service in a community where it is needed.

Chairman Nicolay called for a vote of the Task Force members. A motion was made and seconded to eliminate the public hearing requirements for closures, which was approved by Task Force members Ginsburg, Bedrick, Blumberg, Bonde, Cody, Cohen, Holland, Kane, Mahan, Narang, Pinkner, Rosen, Suldan, Tranter, and Wilson; and opposed by Task Force member Dr. Hussein.

●Clinical Information Technology

Chairman Nicolay said that the next item to be discussed was capital expenditures for clinical information technology that is directly related to patient care. He asked Ms. Barclay to elaborate on the issue. Ms. Barclay said that this comment came from the Maryland Hospital Association, as well as a number of individual hospitals, and CareFirst, as a payer and provider. She stated that the Commission had recently reviewed two CON proposals involving clinical information technology because the expenditures were over the capital threshold. Clinical information technology was not expressly a regulated service under the CON statute.

Dr. Cohen argued that the Commission should expressly state that it does not regulate clinical information systems. In addition, both the hospital providers and the payers agree that the capital threshold should be much higher. If the threshold were raised as proposed, it would be high enough so that information technology systems would not be eligible for review. Mr. Tranter said that the statute is not clear. It exempts business and office equipment and major medical equipment; however, it was written when clinical information systems were not in the conceptual framework and, therefore, are not clearly exempted.

Following discussion, Dr. Cohen made a motion that if the Commission's attorneys determine that it has the authority to require an application for CON for clinical information systems, then the Task Force recommendation is to change the law so that the Commission no longer has that authority. The motion was seconded by Commissioner Ginsburg, and approved unanimously by the Task Force members.

●Specialized Health Care Services

Chairman Nicolay said that the next item for consideration was specialized acute care services and asked Ms. Barclay to set forth the issues for the Task Force. Ms. Barclay said that the Task Force received comments regarding regulating a specific set of highly specialized services: open heart surgery, organ transplant surgery, neonatal intensive care units (NICUs), and burn care. Some commenters said that as medicine and technology have moved forward since those services were identified as being highly specialized and of a nature that the Commission would plan for, other services have been developed that are equally specialized but are not regulated under the CON program, resulting in, perhaps, inconsistency in terms of the resources, skill, and cost of some services that are generally available and not regulated under the CON program, as opposed to those that are regulated. Another point raised was that the Commission should consider a licensure process that would include attention to quality on an ongoing basis, rather than regulating market entry for these services.

Dr. Blumberg said that he would support elimination of CON for these services and the development of a licensure approach. From a consistency standpoint, one could elect to get rid of CON and not establish licensure as a middle point because there are many medical services currently available, and others that have come and gone, where CON was not required.

Dr. Bedrick asked for information concerning the difference between licensure and the CON application process. What is the difference between licensure and the process that includes a critical analysis for a new service? Ms. Barclay responded that CON is concerned with oversight over establishing new programs and making determinations as to whether or not there should be additional new programs. Licensure would not be concerned with establishing new programs, but would be concerned with how those programs, however many there were, would operate. Would they meet quality standards? Would they have appropriate staff? Under a licensure program, there would not be a restriction in terms of the number of new programs developed.

Ms. Bonde asked for more information regarding for which services a revised licensure procedure could be instituted and who would enforce the quality standards. Ms. Barclay replied that the comments received during the Public Forum were not specific. They were general observations that licensure would be a better way to have oversight over specialized services. The assumption would be that the Office of Health Care Quality and the survey process would administer any type of licensure oversight.

Dr. Bedrick expressed grave concern that eliminating the need for CON for certain specialized services like neonatal intensive care begs the question of CON becoming a "certificate of want." From the perspective of licensure, there are mechanisms through the Maryland Institute for Emergency Medical Services Systems (MIEMSS) and the Department of Health and Mental Hygiene (DHMH) for comprehensive reviews for certain levels of neonatal intensive care. The specific volume requirements that have been established for some services, for example, cardiothoracic services, do not necessarily apply to neonatal intensive care. Both the costs and the processes for establishing that kind of special service are dramatic. It would not be well-founded or thoughtful policy to allow individuals or hospitals to set up new services because they want to, and then go through the site visit process, after the service has been established.

Dr. Wilson expressed mixed feelings about this question. He had grave concerns about deregulation, having come from California where a family member had open heart surgery at a hospital that performed barely fifty procedures a year, and whose mortality rate was above six percent. Hospitals with low volume eventually stopped providing those services in California, but in the interim, people were injured and died. To not require a CON for those services is neither in the best interest, nor a good policy decision, for the health of Marylanders

Dr. Cohen said that he has mixed feelings on this subject in part, because some services are overregulated and in part, because some of them are regulated so differently from others. There is not a need determination for NICU services as there is for some of the others. Even though the law is the same, they are treated somewhat differently. With regard to burn care, there are not many hospitals providing services. Open heart surgery has a volume/quality relationship that is manageable through licensure. If quality is the issue, then it can be handled through licensure. Any hospital that has a certain, relatively large volume of coronary patients could provide open heart surgery services. For example, there is a requirement that only one new program at a time in a jurisdiction is allowed. If two hospitals can perform 300 to 500 procedures, why should we have the level of restrictions that exist now in order to achieve the appropriate balance between quality and allowing hospitals to serve their patients?

Mr. Tranter said that the philosophical underpinning for cardiac surgery requirements is that there is a volume/quality relationship and that if these procedures can be performed like any other service, there will be too many of these programs performing too few cases. There are other services in the hospital context that are as sophisticated or, in some instances, more sophisticated than cardiac surgery. He favored the status quo because licensure is a review process initiated after the fact. On balance, there are good arguments that, perhaps, cardiac surgery should not be treated in a specialized manner, but the volume/quality relationship makes sense. He proposed to leave the regulations as they are.

Chairman Nicolay asked if Mr. Tranter intended to support keeping the status quo for all four specialized services. Mr. Tranter replied that his proposal applied to cardiac surgery; however, he was uncertain about burn units, NICU services, and organ transplantation services.

Ms. Bonde asked why it was an acceptable principle for CON to sustain quality in these specialized services, when it had been dismissed in the hospice context. Dr. Cohen said that the reason for addressing the issue of open heart surgery and the potential of CON regulation is the volume/quality relationship. It is not clear that there is literature related to hospice showing that there is a quality/volume relationship.

Dr. Bedrick added that it is also worth pointing out that among the four specialty services, there is significant heterogeneity. They are not a homogenous group. There is a reason in the Baltimore region, in the State of Maryland, that there are very few burn centers. There is a reason that many hospitals want provide open heart surgery services. He thought that a critical analysis of the services continues to be warranted. Not every hospital wants to be a burn unit due to the tremendous outlay of resources for a relatively small number of patients. Dr. Pinkner said that as one who formerly treated burns regularly, he would recommend the elimination of CON regulation for burns, while retaining it for the other three services.

Dr. Blumberg said that Dr. Bedrick's argument was correct, though he would draw the same conclusion. The marketplace has determined that there is no need for many burn units, but is suggesting that more cardiac programs could be supported.

Mr. Tranter said that the volume/quality issue is significant and that licensure would not be able to prevent hospitals that ought not to get into this business from getting into it. Dr. Blumberg added that there are already hospitals in this business that should not be in this business. Because there is not a strong licensure program, there is difficulty in mediating the situation. Mr. Tranter replied that we do have licensure—we have JCAHO and we have hospital licensure—and those mechanisms have not identified that those programs should go away.

Mr. Suldan suggested that it is important to articulate what the principle is and what the principle is not. The principle is not that the next guy will do it worse than I do it now—the market can take care of that. The principle is that if there is a next guy, it will be worse for everybody, and that's the volume/quality relationship. Much of the discussion about hospice related to whether or not the principle applies to hospice, or if it was that the new guys will not do it as well as the existing ones.

Anil K. Narang, D.O. said that the members had discussed comparing quality in CON-related states to quality in non-CON states. He asked if there is a study, especially regarding areas where CON is regulated in acute care services, that a comparison in morbidity or mortality may be drawn with certain states that do not regulate the services? Dr. Cohen observed that with regard to open heart surgery, it is extremely important to note that the nature of the way that CON is applied is very different. For example, Pennsylvania had CON for open heart surgery and then eliminated it. During the time that CON was required, the regulators decided that the number of open heart surgeries required in any market was 350, and then they determined that was the number of services that they would approve. Pennsylvania was listed as a CON-regulated state, but they had a very different process and methodology for determining how many programs there are. Dr. Narang suggested that it might be easier to compare Maryland with the states that do not have CON at all, rather than comparing it with the states that do have CON.

Mr. Rosen said that if there is a CON requirement, then there needs to be a reason for it. He suggested that there are, perhaps, several reasons. One is that if there is a relationship between volume and safety, then it makes sense to restrict the number of providers. That is done through CON and not, in fact, with licensure. For other services, such as hospice, if someone made the case that expanding the number of providers would take certain mission-driven providers out of the system, then that reduces access. CON regulation is not just for safety. It may be for safety reasons, or to protect a mission-driven institution that is meeting a need that the marketplace is not, as well as others. With respect to other situations where there are also safety and volume considerations, then Maryland should consider expanding CON regulation to those services. There is no a reason to say, therefore, that CON should be eliminated for those services identified as having a volume-safety relationship. Inconsistency is not a reason to eliminate CON.

Ms. Mahan said that there are technology and geographic issues associated with NICU and open heart services that are a part of the CON regulatory process. Technology introductions, such as drug eluting stents, have driven down the open heart population in the last few years. Studies have shown that there are quality/volume outcomes and Maryland has had a process in place incorporating those aspects. It would be making a mistake to think that the Task Force should do something in a short period of time different from what has been supported by public opinion at forums and legislatures for years. Commissioner Ginsburg agreed with Ms. Mahan and reiterated his earlier suggestion for reviewing the 2001 study recommendations, determining what is different, and what should be changed, if anything.

Mr. Tranter set forth a continuum of the four options under consideration. One was to leave everything as it is; the next step over was to leave things as they are for cardiac surgery, organ transplant, and NICU, but not burn units; next was to leave things the way they are but, regulate cardiac surgery differently; and finally, on the other end of the continuum, to eliminate CON for all four services.

Dr. Blumberg proposed that CON be eliminated for all four services and that a licensure program be devised in a manner that would ensure the highest quality of these services for Maryland residents.

Dr. Pinkner recommended that the Task Force take a vote on each of the four services separately.

Commissioner Ginsburg asked for more information regarding the procedures for initiating a burn unit and the capital expenditure involved. Without that information, it would be difficult to determinate that CON should be eliminated, in his opinion. Dr. Wilson asked if CON should be eliminated for burn units because not many organizations want to provide the service anyway. Dr. Pinkner doubted that any new burn units would open, due to their costly nature. Ms. Bonde asked if a hospital wanted to open one, why wouldn't they apply for a CON? Dr. Pinkner replied that a CON application is an additional expense for burn centers that are not profitable. Mr. Tranter asserted that if the marketplace is sufficient to control access for burn units, then Maryland doesn't need to regulate market entry. Dr. Wilson asked for information on how many hospitals have applied to open a burn unit in the past 25 years. If none, then what is the reason for the regulation?

Ms. Cody noted that the CON process can bring forth additional helpful information about how a program would work, such as will it be a high quality program; and does it have outreach services that are appropriate for bringing in patients? There are issues beyond the volume/quality relationship that can be addressed in the CON process that can be valuable and provide reasons for continuing CON regulation.

Dr. Blumberg seconded Dr. Pinkner's motion in favor of the task force voting individually on each of the four services.

Dr. Pinkner made a motion to recommend the elimination of CON approval for burn units. This motion was seconded by Mr. Tranter. Task Force members Blumberg, Cohen, Holland, Kane, Mahan, Narang, Pinkner, Rosen, Suldan, Tranter, and Wilson voted in favor of the motion, and Task Force members Bedrick, Bonde, Cody, Ginsburg, and Hussein voted against it. Chairman Nicolay noted that the motion carried.

Dr. Blumberg made a motion to eliminate CON review for organ transplant services. Chairman Nicolay asked if there was a second to the motion and, there being none, the motion died.

Dr. Pinkner made a motion that the Task Force recommends continuation of CON for organ transplant services, which was seconded by Commissioner Ginsburg as well as other task force members.

Dr. Blumberg asked if an organ transplant surgeon at one of the universities moved to another hospital and that hospital was willing to provide the same kind of quality program that it does for all of its other services, and wanted to make the financial expenditure to support that doctor and develop a transplant team, then what would be wrong, from a societal standpoint, if there was an additional choice in the community? Dr. Bedrick replied that the hospital would be welcome to go through the CON process. Dr. Blumberg suggested that marketplace considerations are an important aspect in an institution's decision-making process about providing these services. He suggested that the Task Force should consider consistency and expand CON to anything that is costly or specialized. In his view, there is an inconsistency in the regulation of the four services for historic reasons and the history does not justify the amount of regulation.

Ms. Mahan observed that as a hospital must make a huge commitment in terms of staff resources and finances to provide organ transplant services, there is no reason that it should not go through the regulatory process. Dr. Hussein added that CON is the forum where marketplace issues are discussed and, in the event that forum was taken away, she was not certain that the marketplace would continue to operate as it does today.

Mr. Kane suggested that if CON is a useful forum to get information and to discuss ideas, maybe there needs to be a review of the criteria for how it is applied, not just in the marketplace, additional factors that a facility might have a proposal for. In his view, there are alternative ways, or different criteria, that could be developed through a licensure program.

Ms. Holland asked if a program can apply for a CON for these specialized services at any time, and must it prove need, or can a program only apply for these services when there is a stated service need? Ms. Barclay responded that the answer depends upon the applicable State Health Plan chapter. There are differences in the way the Plan looks at need, depending on the service. There is not one approach that applies in an equivalent fashion to all of the services. The approach in open heart services is to project future utilization and, if certain criteria are met, then to consider a new program. For NICU, there is not a need forecast in the Plan. The Commission's regulation of NICU services is inter-linked to MIEMSS and to DHMH. There is a coordinated process with those two agencies to require new NICU providers to meet certain standards as part of the CON review process. For organ transplant services, there are specific requirements, depending on the organ system, and there are minimum utilization thresholds and criteria that need to be met before a CON application would be considered. Data on organ transplant services are not presently suggesting a need for additional programs due to the supply of organs and general utilization patterns. There is no State Health Plan chapter on burn care.

Chairman Nicolay asked if there was second to Dr. Pinkner's motion to continue CON regulation of organ transplant services. The motion was seconded by Commissioner Ginsburg. It was unanimously approved by all members of the Task Force with the exception of Dr. Blumberg, who abstained.

Commissioner Ginsburg made a motion that the Commission retain the CON program for Open Heart Surgery, which was seconded by Dr. Cohen, who noted that the Task Force had not yet considered changes to the CON standards for open heart surgical services. Mr. Tranter asked Dr. Cohen to state his proposed amendment and Dr. Cohen replied that the Task Force should consider making changes to the State Health Plan standards for open heart services.

Chairman Nicolay stated that proposed changes to the State Health Plan standards would be considered at a subsequent meeting and called for a vote on Dr. Pinkner's motion, which was approved by all of the task force members present with the exception of Dr. Blumberg.

Dr. Bedrick made a motion that the Commission maintain the CON process for neonatal intensive care units.

In response to Mr. Rosen's request that he clarify his views, Dr. Bedrick expressed reservations about changing the current system. The existing NICUs were established prior to the current, well-defined process set forth in the State Health Plan. There are a certain number of neonatal intensive care units that are existent, operational, have been surveyed by MIEMMS and DHMH, and have been found to be doing a good job. Each has received licensure, for lack of a better term, to continue in its role as a neonatal intensive care unit. In Dr. Bedrick's opinion, Maryland should not have uncontrolled propagation of neonatal intensive care units, therefore, the CON regulation should remain.

Dr. Cohen asked if NICU services need to be subject to CON, as opposed to being required to pass the existing MIEMMS and DHMH standards. Dr. Bedrick explained that one of the problems with neonatal intensive care units is that, until recently, hospitals provided the services and wanted recognition that they had done so. The services were uncontrolled in that regard and that process has come to an end. Currently, a hospital can no longer simply start providing neonatal intensive care services. In the absence of the current regulatory process, one of the concerns would be that if a hospital has an obstetrics service, then it would have the freedom to begin providing neonatal intensive care.

Dr. Blumberg said that though he does not practice obstetrics, he chairs the Claims Committee for Med Mutual, which reviews at least one or two obstetrics cases every month. He argued that as a physician and a citizen, if his wife were pregnant again and she wanted to deliver with her obstetrician at a hospital that he or she recommended, then he would want NICU services available at that hospital. NICU services are a part of the continuum of obstetric services in 2005. He supported removing the CON requirement for NICUs and replacing it with MIEMMS and DHMH licensure.

Ms. Cody remarked that the current CON law, as she understands it, does not prohibit a hospital to state very clearly what it is going to do and to demonstrate, up front, its ability to meet those quality standards. In response to Dr. Pinkner's question regarding when accreditation is given, Dr. Bedrick said that there is a current, stable number of neonatal intensive care units in the state that have gone through a DHMH and MIEMMS combined site visit and accreditation process. There are two NICU units in the state in more rural areas, which have been providing neonatal intensive care, are recognized by the state as having provided the services, and under the new rules, are about to go through the site visit process. Those hospitals will be submitting applications to be certified as perinatal centers. Dr. Bedrick did not know the hospitals' status regarding the HSCRC rate designation for neonatal intensive care or a waiver. They are the only two centers that have been recognized for providing NICU services that will be reviewed for perinatal certification.

Dr. Pinkner asked if any hospital, without a CON, could begin offering NICU services and become accredited afterward. Dr. Bedrick replied that the CON applies to neonatal intensive care units in hospitals that are designated Level III, Level III+, and Level IV. This means that they are taking care of babies of a certain gestational age, requiring a certain amount of technology, at a certain birth weight. There is not a CON process for hospitals that are Level I or Level II providers of special care nursery services. Some hospitals in that category are providing services and are ready to make application to go up to the next level of care. They will be required to go through the CON process, and also the MIEMMS-DHMH certification process, in order to change their designation..

Commissioner Ginsburg asked what the standards are for CON for neonatal intensive care units. Dr. Bedrick replied that every hospital that is providing obstetrics would want to have a neonatal intensive care unit, which is a very expensive infrastructure. In the Baltimore metropolitan region, nearly every hospital that provides obstetrics services has a neonatal intensive care unit.

Due to the lengthy discussion and the time of day, Chairman Nicolay suggested that Dr. Bedrick withdraw his motion and that further discussion of neonatal intensive care units be tabled to the next meeting of the Task Force. Dr. Bedrick declined to withdraw the motion.

Mr. Tranter asked for more information regarding NICU services. He asked if there is a volume/quality relationship in terms of providing Level III or higher NICU services. He also asked what is the difference between a Level II program, which a hospital can have without a CON, and a Level III program, for which a CON is required. Dr. Bedrick responded that there is not the amount of data regarding volume for neonatal intensive care services as there has been for open heart services. There have been a number of studies done in California that have shown that the smaller programs do a fine job in neonatal intensive care. In the Baltimore region, outcomes for some units that have an average census of 15 patients are as good as those that have a census of 35 or 40. The argument has been made that the much higher volume units may not do as good a job due to limitation of resources for providing the kind of nursing care that these babies need. Generally, for Level I and Level II units, the obstetric and neonatal units take care of larger, more mature babies. For example, assuming that a term baby is 38 weeks gestation, a Level I unit takes care of all full-term, uncomplicated pregnancies and there are few of those in Maryland. There are slightly more Level II units, which take care of babies from term to thirty-three to thirty-four weeks gestation, who are mildly to moderately premature and may need some supplemental care above and beyond normal newborn care like some oxygen or IV therapy. Units that are designated Level III and higher take care of babies of all gestational ages, have the skilled capability to do mechanical ventilation, and have certain subspecialty services available. The American Academy of Pediatrics and the American College of OB/GYN publishes a document called, "Guidelines for Perinatal Care," which outlines the staffing ratios for normal newborns, mildly sick babies, and more critical babies. In response to Mr. Tranter's questions regarding NICU staffing expertise and ratios of nurses to infants, Dr. Bedrick said that there is a big leap between Level II and going to Level III. There is a much different skill set for Level III units, when staff are taking care of babies weighing, perhaps, two pounds who are sick and on ventilators versus Level II units' staffs taking care of babies who may just have a little oxygen hood around their head.

Chairman Nicolay requested that Dr. Bedrick restate his motion regarding NICU services. Dr. Bedrick said made a motion to maintain the current process for CON for NICU in the current structure, which was seconded by Commissioner Ginsburg. Task Force members Bedrick, Bonde, Cody, Holland, Hussein, Mahan, Narang, Pinkner, Suldan, and Wilson voted in favor of the motion; Task Force members Blumberg and Cohen voted in opposition to the motion; and Task Force members Kane, Rosen, and Tranter abstained.

Mr. Rosen said that he had abstained because he did not understand the standards and did not hear an articulation of why CON should be retained when there is no determination of need. In his view, the regulatory process that was described was not a CON process. Dr. Bedrick replied that the neonatal intensive care units were created prior to the creation of the regulatory process regarding the appropriate and necessary leverage, strength, and oversight. Mr. Rosen made a similar comment related to burn units. He said that in spite of his discomfort due to the absence of Ms. Brown from Johns Hopkins Health System, a burn unit provider, he voted in favor of elimination of CON based on the earlier discussion. If further expert information is offered to the Task Force and the issue is reconsidered, he would be happy to have further information

4. <u>Other Business</u>

There was no other business considered by the Task Force.

5. <u>Adjournment</u>

Chairman Nicolay announced that the next meeting would be held on July 14, 2005 at 1:00 p.m. Mr. Tranter made a motion to adjourn, which was seconded by Ms. Mahan. The Task Force meeting was adjourned at 3:29 p.m.